Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs

DRAFT GUIDANCE

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U.S. Department of Health and Human Services

Office for Human Research Protections **Food and Drug Administration**

August 2016

Contains Nonbinding Recommendations

Draft – Not for Implementation

Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs

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U.S. Department of Health and Human Services

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Guidance for Institutional Review Boards (IRBs)

IRB Written Procedures

This draft guidance, when finalized, will represent the Office for Human Research Protections' (OHRP's) and the Food and Drug Administration's (FDA's) current thinking on this topic. This guidance does not create or confer any rights for or on any person and does not operate to bind OHRP, FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate OHRP or FDA staff responsible for implementing this guidance. If you cannot identify the appropriate OHRP or FDA staff, call the appropriate number listed on the second title page of this guidance.

I. INTRODUCTION

This draft guidance has been prepared jointly by the Department of Health and Human Services (HHS's) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). This guidance is intended for institutional review boards (IRBs) and institutions responsible for review and oversight of human subject research under the HHS or FDA regulations, or both.

This joint draft guidance is intended to assist IRB administrators, IRB chairpersons, and other institutional officials responsible for preparing and maintaining written procedures for the IRB. The guidance provides an IRB Written Procedures Checklist that incorporates the HHS and FDA regulatory requirements for IRB written procedures and additional topics that we recommend including in written procedures. When finalized, this document will supersede OHRP's July 1, 2011 "Guidance on Written IRB Procedures"[1] and FDA's 1998 "Appendix H: A Self-Evaluation Checklist for IRBs,"[2] (formerly part of FDA's Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors).

OHRP's and FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes OHRP's and FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in OHRP and FDA guidance documents means that something is suggested or recommended, but not required.

II. BACKGROUND

OHRP and FDA frequently receive requests for clarification regarding the scope and content of IRB written procedures. We recognize that procedures may vary among institutions and IRBs

[1] http://www.hhs.gov/ohrp/policy/irbgd107.html.
[2] http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm118063.htm.

due to differences in the type of research studies reviewed by the IRB, institutional policy or administrative practices, number of IRBs at the institution, affiliation with an institution, and local and state laws and regulations. In order to provide guidance on the appropriate content of written procedures, while taking into account these variations, we created an IRB Written Procedures Checklist (see section IV) to assist IRBs in preparing and maintaining detailed written procedures suitable for their institutions. **NOTE:** IRB written procedures do not need to follow the order of the items presented in the Checklist and may be integrated to avoid redundancy.

III. DISCUSSION

IRBs that are subject to both the HHS and FDA regulations in Titles 45 (45 CFR Part 46), and 21 (21 CFR Parts 50 and 56), respectively, must comply with the requirements for IRB written procedures in both sets of regulations. The HHS and the FDA regulations[3] require that IRBs follow written procedures for the following specific functions:

- Conducting initial and continuing review of research;
- Reporting findings and actions to the investigator and the institution;
- Determining which projects require review more often than annually;
- Determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;
- Ensuring prompt reporting to the IRB of proposed changes in a research activity, and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects;
- Ensuring prompt reporting to the IRB, appropriate institutional officials, any department or agency head and OHRP for research conducted or supported by HHS, and the FDA for FDA-regulated research of:
    - Any unanticipated problems involving risks to human subjects or others;
    - Any instance of serious or continuing noncompliance with the applicable HHS and FDA regulations or the requirements or determinations of the IRB;
    - Any suspension or termination of IRB approval.

HHS and FDA regulations[4] do not provide additional detail on the content of IRB written procedures, which gives IRBs the flexibility to establish procedures best suited to their own operations.

[3] 45 CFR 46.103(b)(4) and (5), 21 CFR 56.108(a) and (b).
[4] *Ibid*.

Developing robust IRB written procedures involves a comprehensive and critical assessment of the IRB's responsibilities, functions, operations, and organizational structure. IRB written procedures should be sufficiently detailed so that IRB members and administrative staff understand how to carry out their duties consistently and effectively in ways that ensure that the rights and welfare of subjects are protected, and that the IRB operates in compliance with the regulations. When preparing IRB written procedures, IRBs should identify who carries out specific duties by reference to position title (e.g., IRB Administrator) rather than by employee name in order to avoid the need to update written procedures if an employee's duties change or there are changes in IRB staff.

IRBs should consider making their written procedures available to investigators to ensure investigators are aware of the IRB's requirements, and to facilitate investigator compliance with IRB requirements. Step-by-step operational details in written procedures also help regulators[5] understand how the IRB operates and fulfills its regulatory responsibilities. OHRP and FDA have observed that some IRB written procedures simply reiterate the regulations, which is an approach that does not provide sufficient detail about the IRBs' operations necessary to meet the regulatory requirements for written procedures.

Both OHRP and FDA have a range of guidance documents[6] that cover a variety of topics that may be useful to IRB administrators, IRB chairpersons, and other institutional officials when preparing written procedures for the IRB. For example, guidance on IRB continuing review of research[7] speaks to key considerations for the IRB at the time of continuing review and offers suggestions about written procedures specific to continuing review. These key considerations and suggestions should be incorporated into the IRB written procedures and used to differentiate procedures followed by the IRB at the time of continuing review from procedures followed by the IRB at the time of initial review.

The IRB Written Procedures Checklist is designed to prompt a thorough evaluation of procedures essential for ensuring the protection of human research subjects. The IRB's written procedures should be reviewed on a regular basis and updated as necessary to ensure they reflect the IRB's current processes. When IRBs develop and follow clear written procedures, we believe there is a greater likelihood that the rights and welfare of human subjects are protected.

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[5]FDA and OHRP may evaluate the IRB's written procedures to determine if IRBs are operating in compliance with current regulations and statutory requirements [refer to 45 CFR 46.115(b) and 21 CFR 56.115(b)].

[6]http://www.hhs.gov/ohrp/policy/index/index.html, http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm, http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm.

[7]http://www.hhs.gov/ohrp/policy/continuingreview2010.html, http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf.

IV. IRB WRITTEN PROCEDURES CHECKLIST

The IRB Written Procedures Checklist included below identifies the HHS and FDA regulatory requirements and recommendations for IRB written procedures. The regulatory requirements are denoted in the Checklist as headers to sections I, II, III and IV. The Checklist also includes recommendations on topics to cover in written procedures to ensure an adequate description of IRB functions and operations. For example, if an IRB reviews studies involving children as subjects, the IRB should have written procedures that describe how the IRB ensures the review of such research is in accordance with the regulatory requirements for the additional protections for children (45 CFR Part 46 Subpart D, or 21 CFR Part 50 Subpart D). For this reason, the Checklist also includes footnotes that cross-reference relevant regulations, which we recommend IRBs consider addressing in written procedures.

Although written procedures for items in the Checklist may not be required by the regulations (e.g., administrative support staff duties), such items are appropriate to consider when developing an IRB's comprehensive written procedures.

The amount and nature of the detail included in IRB written procedures may vary across IRBs and not all of the topics listed in the Checklist may be applicable to all IRBs. The institution and the IRB may also determine that, based on the unique aspects of the research reviewed by the IRB, additional topics not included in the Checklist should be included in their IRB written procedures (e.g., written procedures related to how the IRB interacts with an Institutional Biosafety Committee, or a Radioactive Drug Research Committee).

Finally, we note that several of the activities described below in the Checklist are required by the regulations but the HHS and FDA regulations do not explicitly require that an IRB establish and maintain a written procedure *for conducting the activity*. However, we recommend IRBs consider addressing these activities in the written procedures.

IRB WRITTEN PROCEDURES CHECKLIST

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
I. Conducting Initial and Continuing Review of Research and Reporting IRB Findings and Actions to the Investigator and the Institution [45 CFR 46.103(b)(4)(i), 21 CFR 56.108(a)(1)]			
1. The institution's process for determining whether a study is subject to review by the IRB (e.g., what types of studies must be reviewed, which regulations apply).			
2. The institution's process for determining which HHS-conducted or -supported research studies qualify as exempt from the HHS regulations.			
3. Conducting review at a meeting of the convened IRB.[8] Operational details should include: • A list of documents to be submitted to the IRB (e.g., protocol, informed consent form, investigator brochure, recruitment materials, HHS-approved protocol and sample informed consent form). • Timelines for receipt of submissions, scheduling IRB review, and document distribution to IRB members. • The type of reviewer system utilized by the IRB at a convened meeting (e.g., primary reviewer(s)). • A list of documents routinely distributed to all IRB members and a list of documents distributed to any specific IRB members (e.g., primary reviewer(s)). • The range of possible actions that can be taken by the IRB (e.g., approve, require modifications in to secure approval, disapprove, suspend or terminate approval of a study).			
4. Conducting review via expedited review procedures.[9] Operational details should include: • A list of documents required for submission and provided to the person conducting the expedited review. • Timelines for receipt of submissions and scheduling expedited review. • Who confirms the study qualifies for expedited review and who conducts the expedited review. • The range of possible actions that can be taken by the person conducting the expedited review (e.g., approve, require modification in to secure approval, or if not approvable, referral to the full board for review). • The method used for keeping all members advised of research proposals approved via expedited review.			

[8]See 45 CFR 46.108(b), 21 CFR 56.108(c).
[9]See 45 CFR 46.110, 21 CFR 56.110.

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
5. Determining that the criteria for IRB approval of research are met.[10] Operational details should include: • How the IRB determines that all approval criteria are satisfied before approving a research study. • Where the IRB documents its review determinations (e.g., in the meeting minutes or elsewhere in the IRB records). • How the IRB assesses risks of the research, including whether risks can be minimized through appropriate measures. • How the IRB assesses any potential benefits to subjects or others that may be reasonably expected to result, and whether this provides a reasonable basis for assuming the risks of the research. • How the IRB determines whether the selection of subjects is equitable (e.g., the adequacy of the inclusion and exclusion criteria). • How the IRB assesses the informed consent process and determines that informed consent is sought and documented in accordance with other applicable regulations. • How the IRB determines whether provisions to monitor data collected are adequate to ensure the safety of subjects, and provisions to protect the privacy of subjects and confidentiality of the data are adequate, where appropriate.			
6. Reviewing and approving the informed consent form and the informed consent process.[11] Operational details should include: • How the IRB ensures that all of the required elements of consent, and any additional elements of consent are included. • The document control system used by the IRB to assist the investigator and study staff in presenting subjects with the current IRB-approved consent form. • How the IRB reviews the informed consent process and assesses provisions for translations of the informed consent form for non-English speaking subjects, when applicable. • At the time of continuing review, how the IRB determines whether the IRB-approved informed consent form requires revision. • For HHS-conducted or -supported research, the IRB's process for approving waivers or alterations of the consent procedure. • For both HHS-conducted or -supported research and FDA-regulated research, the IRB's process for approving waivers of documentation of consent.			
7. Describing how the IRB decides whether additional safeguards should be put in place when the study involves subjects who are likely to be vulnerable to coercion or undue influence.[12]			

[10]See 45 CFR 46.111, 21 CFR 56.111.
[11]See 45 CFR 46.111(a)(4) and (5), 21 CFR 56.111(a)(4) and (5), 45 CFR 46.116, 21 CFR 50.20, 21 CFR 50.25, 45 CFR 46.117, 21 CFR 50.27.
[12]See 45 CFR 46.111(b), 21 CFR 56.111(b).

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
8. Reviewing any study requesting an Exception from Informed Consent Requirements for Emergency Research.[13] Operational details should include a description of how the IRB review meets the range of regulatory requirements for emergency research (e.g., community consultation and public disclosure). **NOTE:** FDA has guidance specific to exception from informed consent requirements for emergency research that may be helpful when addressing this topic in the IRB written procedures.[14]			
9. For FDA-regulated research, assessing whether the investigator and/or the sponsor determined that an IND or IDE is required for the proposed study if applicable, and the basis for this determination.[15]			
10. For FDA-regulated medical device research, making and documenting the significant/nonsignificant risk (SR/NSR) determination.[16]			
11. For HHS-conducted or -supported research, determining the applicability of additional protections for Pregnant Women, Human Fetuses and Neonates, and for Prisoners, found in 45 CFR 46 Subparts B and C respectively.[17]			
12. Ensuring the IRB reviews research involving children as subjects in accordance with applicable regulations.[18] Operational details should include a description of how the IRB review meets the range of regulatory requirements for research involving children (e.g., findings related to the category of research, and how to handle research that falls into categories 45 CFR 46.407 or 21 CFR 50.54).			
13. Reviewing the qualifications of the investigator(s) and study staff, and the adequacy of the site where the research will be conducted.			
14. Assessing and managing investigator conflict of interest, if any.			
15. Determining the applicability of state and local laws.			
16. Determining and documenting the effective date of initial approval, and calculating the date for subsequent continuing review.			

[13]See the Secretarial Waiver for OHRP at http://www.hhs.gov/ohrp/policy/hsdc97-01.html, and see 21 CFR 50.24 for FDA-regulated studies.
[14]See FDA Guidance for Exception from Informed Consent Requirements for Emergency Research at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm249673.pdf.
[15]See 21 CFR 312.2, 812.2.
[16]See 21 CFR 56.108(a)(1), 56.115(a)(6), 812.2, 812.66.
[17]See 45 CFR 46 Subparts B and C.
[18]See 45 CFR 46 Subpart D, 21 CFR 50 Subpart D, 45 CFR 46.111(b), 21 CFR 56.111(c).

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
17. IRB member attendance required to conduct a convened meeting.[19] Operational details should include: • How the IRB convenes the members of the IRB for a meeting (e.g., in person, via videoconferencing or other mechanism). • The number of members on the IRB, how quorum is defined and maintained, and the process the IRB follows if quorum is lost during a meeting. • Prohibition of proxy votes. • Managing any IRB member or alternate member conflict of interest.			
18. Communicating the IRB's findings and actions, and any decision to approve or disapprove the proposed research activity or of modifications required to secure approval of the proposed research activity in writing to the investigator and the institution.[20] Operational details should include: • A description of the written information the IRB provides to the investigator regarding its findings and actions (e.g., approve, require modification in to secure approval, disapprove). • A description of which institutional office(s) and official(s) are notified of the IRB's findings and actions. • How notifications to investigators and the institution are communicated, including the associated timelines for notifications. • How modifications or clarifications required by the IRB as a condition of approval are communicated in writing to the investigator. • How the IRB subsequently reviews and acts upon the investigator's response to any required modifications or clarifications, and the associated timelines for the investigator's response. • How the IRB communicates the reasons for a decision to disapprove, and the process followed to allow the investigator to respond.			
19. Tracking study approvals and scheduling continuing review to prevent lapses in IRB approval, including procedures to be followed if there is a lapse in IRB approval.			
20. For FDA-regulated research, reviewing the emergency use of a test article.[21]			
21. For FDA-regulated research, reviewing a request for expanded access or treatment use.[22]			
22. For FDA-regulated research, reviewing a request for the use of a Humanitarian Use Device (HUD).[23]			

[19]See 45 CFR 46.108(b), 21 CFR 56.108(c).
[20]See 45 CFR 46.103(b)(4)(i), 21 CFR 56.108(a)(1), 45 CFR 46.109(d), 21 CFR 56.109(e).
[21]See 21 CFR 50.23, 56.102(d), 56.104(c).
[22]See 21 CFR 312.305(c)(4), 812.36.
[23]See 21 CFR 814.124.

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
23. For FDA-regulated in vitro diagnostic (IVD) research, IRB considerations of the use of leftover specimens without informed consent, when the specimens used for IVD development are not individually identifiable. **NOTE:** FDA has guidance specific to informed consent for IVD device studies using leftover human specimens that are not individually identifiable.[24]			
24. Handling subject complaints, problems, concerns and questions about rights as a research subject.			
25. Implementing cooperative IRB review arrangements (including reliance on review by another qualified IRB, joint review, or any similar arrangement to avoid duplication of effort, procedures used to determine which studies qualify for cooperative review, the role of the institution and the institution's IRB in this type of review process, and documenting arrangements in written agreements).[25] **NOTE:** FDA has guidance specific to using a centralized IRB review process in multicenter clinical trials.[26]			
II. Determining Which Projects Require Review More Often than Annually and Determining Which Projects Need Verification from Sources Other than the Investigator that No Material Changes Have Occurred Since Previous IRB Review [45 CFR 46.103(b)(4)(ii), 21 CFR 56.108(a)(2)]			
26. Deciding which research studies require review more often than annually and the criteria used in the determination.[27] Operational details should include: • Specific criteria used by the IRB to determine the approval period (e.g., the nature of the study and risks posed by the study; the degree of uncertainty regarding the risks involved; the vulnerability of the subject population; the experience of the investigator; the IRB's previous experience with the investigator and/or sponsor; the projected rate of enrollment; whether the study involves novel therapies). • Where the IRB documents its determinations about the approval period (e.g., in the IRB meeting minutes or elsewhere in the IRB records). • How the IRB communicates its determinations regarding the approval period to the investigator (e.g., written notice of approval correspondence).			

[24]See FDA Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071265.pdf.
[25]See 45 CFR 46.114, 21 CFR 56.114.
[26]See FDA Guidance for Using a Centralized IRB Review Process in Multicenter Clinical Trials at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127013.pdf.
[27]See 45 CFR 46.103(b)(4)(ii), 21 CFR 56.108(a)(2).

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
27. Deciding which projects need verification from sources other than the investigator (such as the sponsor, or other third party) that no material changes have occurred since previous IRB review and the criteria used in the determination.[28] Operational details should include the specific criteria used by the IRB to determine which projects require verification (e.g., randomly selected projects, complex projects involving risk to subjects, projects conducted by investigators who previously failed to comply with the regulations or the requirements or determinations of the IRB, projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources).			
III. Ensuring Prompt Reporting to the IRB of Proposed Changes in a Research Activity, and Ensuring that Changes in Approved Research, During the Period for Which IRB Approval Has Already Been Given, May Not be Initiated Without IRB Review and Approval Except Where Necessary to Eliminate Apparent Immediate Hazards to the Human Subjects [45 CFR 46.103(b)(4)(iii), 21 CFR 56.108(a)(3) and (4)]			
28. Informing investigators they may not implement any changes in research activities without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects.[29] Operational details should include: • How the IRB informs investigators about not implementing changes to research without prior IRB review and approval (e.g., through training programs and materials for investigators, specific directives included in approval letters to investigators). • Steps taken to ensure that changes in research are being reported to the IRB prior to implementation (e.g., random audits of research records).			
29. Receiving and processing materials about changes in research. Operational details should include: • What qualifies as a minor change in research. • A list of documents to be submitted to the IRB (e.g., summary of changes to the protocol, amended protocol). • Timelines for receipt of submissions, scheduling IRB review, and document distribution. • Criteria used to determine whether full board review is required or whether the changes qualify for expedited review procedures. • How the IRB determines whether the IRB-approved informed consent form requires revision.			

[28]See 45 CFR 46.103(b)(4)(ii), 21 CFR 56.108(a)(2).
[29]See 45 CFR 46.103(b)(4)(iii), 21 CFR 56.108(a)(3) and (4).

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
30. Communicating to the investigator and the institution the IRB's decision to approve or disapprove the proposed change in research activity or of modifications required to secure approval of the proposed change in research activity.[30] Operational details should include: • How modifications or clarifications required by the IRB as a condition of approval are communicated in writing to the investigator. • How the IRB subsequently reviews and acts upon the investigator's responses to any required modifications or clarifications, and the associated timelines for the investigator's response. • How the IRB communicates the reasons for a decision to disapprove the change in research activity, and the process followed to allow the investigator to respond.			
IV. Ensuring Prompt Reporting to the IRB, Appropriate Institutional Officials, Any Department or Agency Head, OHRP and FDA of Any Unanticipated Problems Involving Risks to Human Subjects or Others, Any Instance of Serious or Continuing Noncompliance with the Applicable HHS and/or FDA Regulations, or the Requirements or Determinations of the IRB, and Any Suspension or Termination of IRB Approval [45 CFR 46.103(b)(5)(i) and (ii), 21 CFR 56.108(b)(1)(2) and (3)]			
31. Reviewing information about unanticipated problems involving risk to human subjects or others.[31] Operational details should include: • What constitutes an unanticipated problem involving risk to subjects or others, including adverse events that require reporting to the IRB. • Specific documents to be submitted to the IRB regarding an unanticipated problem (e.g., written summary of the unanticipated problem, the outcome, and any steps taken to prevent recurrence). • Process for reviewing unanticipated problems and the range of actions the IRB may take based on the review. • Determining whether the IRB-approved informed consent form requires revision based on the information about the unanticipated problem.			
32. Reviewing information about serious or continuing noncompliance with the regulations or IRB requirements and determinations.[32] Operational details should include: • What constitutes serious or continuing noncompliance that requires reporting to the IRB. • Specific documents to be submitted to the IRB regarding serious or continuing noncompliance (e.g., written summary of the noncompliance, the outcome, and any steps taken to prevent recurrence). • Process for reviewing reports of serious or continuing noncompliance and the range of actions the IRB may take based on the review. • Determining whether the IRB-approved informed consent form requires revision based on the information about the serious or continuing noncompliance.			

[30]See 45 CFR 46.109(d), 21 CFR 56.109(e).
[31]See 45 CFR 46.103(b)(5)(i), 21 CFR 56.108(b)(1).

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
33. Identifying who (e.g., the investigator, institutional office or institutional official) is responsible for promptly reporting to the IRB, appropriate institutional officials, any department or agency head, OHRP and/or FDA of any:[33] • Unanticipated problems involving risk to human subjects or others. • Serious or continuing noncompliance. • Suspension or termination of IRB approval.			
34. Suspending or terminating approval of research that is not being conducted in accordance with the regulations or IRB requirements.[34] Operational details should include: • When the IRB will consider suspending or terminating IRB approval. • Consideration of what happens to subjects already enrolled in the study if the study is suspended or terminated. • How subjects are informed of the suspension or termination. • Orderly termination of the study, or transfer of the study or study subjects, if applicable.			
35. The timelines required for reporting each type of reportable event to the IRB, to the appropriate institutional officials, any department or agency head, OHRP and/or FDA.[35]			
V. ADDITIONAL CONSIDERATIONS AND SUGGESTIONS FOR POLICIES/PROCEDURES:			
A. **Scope and Authority**			
36. The scope of the IRB written procedures (e.g., who the written procedures apply to, what happens if the written procedures are not followed, who is responsible for preparation and maintenance, including who writes, revises, and approves the written procedures, and how often written procedures are reviewed and updated).			
37. The institutional authority under which the IRB is established and empowered, and the independence afforded the IRB to carry out its duties.			
38. The ethical principles which govern the IRB in assuring that the rights and welfare of subjects are protected.			
39. Important regulatory definitions that guide the IRB's review processes and procedures (e.g., the definition of research, clinical investigation, human subject, minimal risk).			
40. Other relevant federal regulations that may apply to human subject research (e.g., Health Insurance Portability and Accountability Act regulations, Department of Defense regulations).			

[32]See 45 CFR 46.103(b)(5)(i), 21 CFR 56.108(b)(2).
[33]See 45 CFR 46.103(b)(5)(i) and (ii), 21 CFR 56.108(b)(1)(2) and (3).
[34]See 45 CFR 46.113, 21 CFR 56.113.
[35]See 45 CFR 46.103(b)(5)(i) and (ii), 21 CFR 56.108(b)(1)(2) and (3).

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
41. Which institutional office(s) or official(s) is responsible for further review and approval, or disapproval of research that is approved by the IRB[36] (including that no institutional official may approve research that has not been approved by the IRB).			
42. The IRB's relationship to the administration of the institution, the other committees and department chairpersons within the institution, the research investigators, other institutions, and the regulatory agencies.			
B. IRB Membership			
43. The number of IRB members required to serve on the IRB.[37]			
44. Ensuring diversity in the IRB membership (e.g., representation by both genders, multiple professions, scientific and nonscientific members, nonaffiliated members).[38]			
45. Selecting and appointing the IRB chairperson, the members, and alternate members, if any, including: • The length of term or service, description of duties, attendance requirements, and performance evaluation. • The qualifications of the IRB chairperson, members and any alternates, including which alternates can substitute for which IRB members. • Determining which members of the IRB, and alternates, are categorized as scientist, nonscientist, and nonaffiliated members.			
46. Defining what constitutes conflict of interest for the IRB chairperson, members, alternates, and how the IRB manages any such conflict of interest (including recusal from the meeting to ensure that a conflicted chairperson, member, or alternate does not vote or count towards the quorum).[39]			
47. Training and education of the IRB chairperson, IRB members, alternates, administrative support staff, and investigators (including any orientation, continuing education, and a list of any reference materials provided as a resource).			
48. Determining which member(s) may be designated by the IRB chairperson to perform expedited review on behalf of the IRB, and the criteria used to select such designee(s).			
C. IRB Functions and Operations			
49. Administrative support staff duties.			

[36]See 45 CFR 46.112, 21 CFR 56.112.
[37]See 45 CFR 46.107(a), 21 CFR 56.107(a).
[38]See 45 CFR 46.107, 21 CFR 56.107.
[39]See 45 CFR 46.107(e), 21 CFR 56.107(e).

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
50. Any additional IRB considerations or requirements when reviewing sponsor-investigator research.			
51. Keeping the IRB informed of study completion and close out.			
52. The use of consultants by the IRB[40] (including a description of the IRB's process to identify the need for a consultant, to choose a consultant, and to include the consultant in the review of research, ensuring that the consultant does not vote or count towards the quorum).			
53. Registering the IRB and maintaining IRB registration[41] through the HHS Internet-based registration system.			
54. Informing investigators of the IRB requirements and procedures (e.g., posting the information on a website accessible to the investigators, providing an informational packet to each investigator).			
55. Contingency plans for transferring oversight of one or more studies to another institution or IRB in the event that the IRB is unable to continue oversight of the study (e.g., the IRB closes, suffers loss due to fire, natural disaster). **NOTE:** FDA has guidance on considerations when transferring clinical investigation oversight to another IRB[42].			
D. IRB Records			
56. A list of the records maintained by the IRB (including research proposals reviewed, scientific evaluations, approved sample consent documents, progress reports submitted by the investigators, reports of injuries to subjects, minutes of meetings, records of continuing review activities, copies of all correspondence between the IRB and the investigators, the IRB membership rosters, IRB written procedures, and statements of significant new findings provided to subjects).[43]			
57. A description of where records are stored (e.g., on site, off-site archives), and how records are stored (e.g., hard copy, electronic or both).			
58. Preparing and maintaining minutes of IRB meetings (including documentation of attendance at the meeting, actions taken by the IRB, the vote on these actions including the number of members voting for, against and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution).[44]			

[40]See 45 CFR 46.107(f), 21 CFR 56.107(f).
[41]See 45 CFR 46 Subpart E, 21 CFR 56.106.
[42]See FDA Guidance for Considerations When Transferring Clinical Investigation Oversight to Another IRB at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM307779.pdf.
[43]See 45 CFR 46.115(a), 21 CFR 56.115(a).
[44]See 45 CFR 46.115(a)(2), 21 CFR 56.115(a)(2).

IRB ACTIVITY	WRITTEN PROCEDURE? Check *yes* if the IRB has a written procedure on this topic and *no* if it does not.		
	YES	**NO**	**NOTES**
59. Ensuring that records are retained for at least 3 years after completion of the research and that they are organized and accessible for inspection.[45]			

[45]See 45 CFR 46.115(b), 21 CFR 56.115(b).